REMARKS/ARGUMENTS

Reconsideration of this application and entry of the foregoing amendments are respectfully requested.

Claims 1 and 20 have been amended to refer to individuals with chronic HBV infection. Support for the revision can be found, for example, at page 4, last paragraph. Claims 5-12 and 22 have been revised to define the invention with additional clarity.

Claims 1, 4-12, 20 and 22 stand rejected under 35 U.S.C 112, first paragraph, as allegedly being non-enabled. Withdrawal of the rejection is in order for the reasons that follow.

In rejecting the claims as non-enabled, the Examiner contends that "one of ordinary skill in the art practicing the claimed method would not know if an individual recovered or responded to treatment." Applicants respectfully disagree.

At the outset, Applicants direct attention to the fact that that the claims as now presented relate to individuals with chronic HBV infection. The art demonstrates that chronic HBV patients, unlike acute HBV patients, do not exhibit spontaneous recovery. For example, Wei et al state at page 280, first paragraph:

> *Ten chronic hepatitis B inpatients were divided into two groups: one group was healthy chronic carriers (Figure 6B) who were seropositive HBeAg and high level of HBV-DNA and preS1 antigen; the other group was chronic hepatitis B patients (Figure 6C) who had seropositive anti-HBe and low level of HBV-DNA and preS1 antigen during the course of the disease. During follow-up period, anti-preS1 antibodies were not found and there were no apparent improvement in both groups.*

[Emphasis added.]

In other words, none of the ten chronic HBV patients investigated in Wei et al showed any improvement or recovery, nor did these chronic HBV patients display antibodies which react

to any epitope of preS1 (21-119). Wel et al, therefore, teaches that chronic HBV patients do not spontaneously recover from the HBV infection.

The instant specification demonstrates that chronic HBV patients who will improve when treated with IFNα can be identified in advance by the presence of anti-preS1 (94-117) antibodies.

Since Wei et al teach that chronic HBV patients do not recover spontaneously, it will be apparent that any improvement in the condition of chronic HBV patients treated with IFNα must be a response to that treatment as it could not be due to spontaneous recovery.

The skilled person wishing to practice the claimed invention would, therefore, not be required to distinguish between "actual response to lFNα treatment" and "recovery" since spontaneous recovery does not occur in chronic HBV patients. Thus, any improvement seen in such patients treated with IFNα must be a response to the IFNα treatment. Stated otherwise, one of ordinary skill in the art would know that a chronic HBV patient whose condition improved following IFNα treatment displayed an actual response to IFNα treatment.

The Examiner is urged to give careful consideration to the foregoing. It is believed that, having done so, the Examiner will find withdrawal of the rejection to be in order and the same is requested.

The Examiner's attention is directed to the Information Disclosure statement submitted currently herewith.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

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